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EXAMINER

THANH, QUANG D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/917,655

Applicant(s)

BOEKSTEGERS ET AL.

Examiner

Quang D. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 3, 8, 16, 19, 30 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/31/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: AO in fig. 1. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: "PTFE" (p. 8-9 and 11) should be spelled out completely. Appropriate correction is required.

### ***Claim Objections***

3. Claims 3,8,16,19,30 and 35 are objected to because of the following informalities: "PTFE" should be spelled out completely. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1- 3, 9-15, 29-30 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Phelps et al. (6,290,728 B1).

6. Re claim 1, Phelps discloses a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract), comprising:

providing a stent 20 having sufficient strength to resist deformation from contractile cardiac forces and flexibility in a compressed and a deployed state to permit passage to a myocardial site and remain patent when implanted (figs. 5-8, col. 6, lines 15-45);

delivering the stent in the compressed state into a passage at the myocardial site (fig. 7); and

expanding the stent to deploy it in the passage (fig. 8).

7. Re claims 2-3, 9-15, 29-30, 36, Phelps discloses (claims 2-3 and 29-30) the stent includes a covering of PTFE material (col. 6, lines 57-60); (claims 9-10 and 36) the stent includes flared ends 28 (fig. 8), the flared ends are placed in the passage to face both the coronary vessel and the heart wall (fig. 8, col. 6, lines 42-45); (claims 11-12) the coronary vessel is a coronary artery and the heart chamber is a left ventricle (abstract); (claim 13) the myocardial site is distal to a coronary blockage (col. 3, lines 63-67); (claim 14) the coronary blockage is a partial blockage (col. 4, lines 47-57); (claim 15) delivering the stent includes delivering the stent percutaneously (using a catheter delivering device in fig. 5).

8. Claims 1, 9-15, 29, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Knudson et al. (5,755,682).

9. Re claims 1 and 29, Knudson discloses a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract, fig. 12, and col. 13, lines 16-23), comprising:

providing a stent 10 with intraventricular portion 61 having sufficient strength to resist deformation from contractile cardiac forces (col. 14, lines 17-21) and flexibility in a compressed and a deployed state to permit passage to a myocardial site and remain patent when implanted (figs. 14D, 15A-B, col. 24, lines 58-64); a covering 18 (col. 14, lines 1-10);

delivering the stent in the compressed state into a passage at the myocardial site (fig. 14B); and

expanding the stent to deploy it in the passage (fig. 14C).

10. Re claims 9-15 and 36, Knudson also discloses (claims 9-10 and 36) the stent includes a flared end (tongue) the flared end is placed in the passage to face the coronary vessel (col. 9, lines 12-15); (claims 11-13) the coronary vessel is a coronary artery, the heart chamber is a left ventricle and the myocardial site is distal to a coronary blockage (col. 5, lines 53-58); (claim 14) the coronary blockage is a partial blockage (col. 13, lines 44-46); (claim 15) delivering the stent includes delivering the stent percutaneously (using a catheterization method).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 4-8, 16-28 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al. in view of Lee (5,123,917).

13. Re claims 4 and 31, Phelps suggests that the inner surface of the stent can be lined with PTFE (col. 6, lines 57-60) but does not disclose explicitly that the outside surface is also covered with PTFE. However, Lee teaches a graft A having an inner layer 10 and outer layer 20, both layers being made of PTFE (fig. 4, col. 4, lines 49-68 and col. 5, lines 1-3) covering the stent member 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device of Phelps, to include outer layer of PTFE as well as an inner layer of the same material, as suggested by Lee, for the purpose of enhance vascular patency and reducing immunogenic response (col. 4, lines 54-57).

14. Re claims 5-8,16-22, and 32-35, Lee also discloses the stent includes a hemocompatible and anti-thrombogenic coating of heparin on the inside surface of the stent (col. 4, line 57-64).

15. Re claims 23-28, Phelps also discloses (claims 23-24) the stent includes a flared end 28 (fig. 8), the flared ends are placed in the passage to face both the coronary vessel and the heart wall (fig. 8, col. 6, 42-45); (claims 25-26) the coronary vessel is a

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coronary artery and the heart chamber is a left ventricle (abstract); (claim 27) the myocardial site is distal to a coronary blockage (col. 3, lines 63-67); (claim 28) the coronary blockage is a partial blockage (col. 4, lines 47-57).

16. Claims 3-8, 16-28, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. in view of Lee.

17. Re claims 3-4 and 30-31, Knudson discloses the claim invention except that the covering does not include expandable PTFE. However, Lee teaches a graft A having an inner layer 10 and outer layer 20, both layers being made of PTFE (fig. 4, col. 4, lines 49-68 and col. 5, lines 1-3) covering the stent member 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device of Phelps, to include inner layer of PTFE as well as an outer layer of the same material, as suggested by Lee, for the purpose of enhance vascular patency and reducing immunogenic response (col. 4, lines 54-57).

18. Re claims 5-8, 16-22, and 32-35, Lee also discloses the stent includes a hemocompatible and anti-thrombogenic coating of heparin on the inside surface of the stent (col. 4, line 57-64).

19. Re claims 23-28, Knudson also discloses (claims 23-24) the stent includes a flared end (tongue) the flared end is placed in the passage to face the coronary vessel (col. 9, lines 12-15); (claims 25-27) the coronary vessel is a coronary artery, the heart chamber is a left ventricle and the myocardial site is distal to a coronary blockage (col.

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5, lines 53-58); (claim 28) the coronary blockage is a partial blockage (col. 13, lines 44-46).

### ***Double Patenting***

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 29-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,290,728 in view of Lee.

22. Re claim 29-31, claims 1-2 of U.S. Patent No. 6,290,728 disclose the claimed invention except for a covering that includes expandable PTFE. However, Lee teaches a graft A having an inner layer 10 and outer layer 20, both layers being made of PTFE (fig. 4, col. 4, lines 49-68 and col. 5, lines 1-3) covering the stent member 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device of Phelps, to include inner layer of PTFE as well as an outer



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layer of the same material, as suggested by Lee, for the purpose of enhance vascular patency and reducing immunogenic response (col. 4, lines 54-57).

23. Re claims 32-35, Lee also discloses the stent includes a hemocompatible and anti-thrombogenic coating of heparin on the inside surface of the stent (col. 4, line 57-64).

24. Re claim 36, claim 1 of U.S. Patent No. 6,290,728 discloses a flared end (attachment mechanism on at least one end).

### ***Conclusion***

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilk et al. (6,254,564 B1) discloses a left ventricular conduit with blood vessel graft. Ragheb et al. (6,299,604 B1) discloses a coated implantable medical device. Tweden et al. (6,406,488 B1) discloses a transmyocardial implant. Eno et al. (6,409,697 B2) discloses a transmyocardial implant with forward flow bias.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

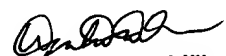
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh  
Patent Examiner  
Art Unit 3764



October 2, 2002



Danton D. DeMille  
Primary Examiner